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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,097	09/10/2003	Rainer Naeff	CCS-202-CON	4324

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
10/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,097	NAEFF ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,16 and 19-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-16 and 19-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 2-12-09 is acknowledged.

Claims included in the prosecution are 15-16 and 19-23.

In view of the amendment, the 112 rejection is withdrawn.

Claim Rejections - 35 U.S.C. § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 15-16 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over either JP 08 231417 or Maitani (J. of Pharmaceutical Sciences, 1996) by themselves or in view of Collins (5,874,075) further in view of JP 61097229 (all are of record).

JP 147 and Maitani disclose liposomes containing erythropoietin. The liposome lipids include synthetic lecithin and cholesterol and phosphate buffer (note the abstract of JP; abstract and Experimental section in Maitani). As well known in the art, liposomal compositions have two aqueous compartments, one within the bilayer and the other

outside the bilayer and the hydrophilic compounds are generally added to the hydrating medium such that part of it is encapsulated in the aqueous compartment within the liposome and unencapsulated active agent is in the outer aqueous medium. In both JP and Maitani, the unencapsulated erythropoietin is removed by filtration. However, it would have been obvious to one of ordinary skill in the art not to remove the compound is such is desired.

Collins as pointed out before teaches liposomal compositions wherein hematopoietic factors including erythropoietin are attached to the surface of the liposomes. The phospholipids include dipalmitoylphosphatidic acid. The liposomes further contain PEG (stabilizer) and a phosphate buffer. According to Collins, such an attachment stabilizes the proteins such as erythropoietin. One of ordinary skill in the art would be motivated not to remove the external erythropoietin since Collins teaches that erythropoietin outside the liposomes stabilizes such proteins. JP, Maitani and Collins do not teach the inclusion of glycine in the liposomal formulations. Such an inclusion however, would have been obvious to one of ordinary skill in the art in view of JP 229, which teaches that glycine is a stabilizer for erythropoietin (note the abstract).

Applicant's arguments have been fully considered, but are not persuasive. Applicant argues that the claimed liposomal based composition is based on the unexpected discovery that the liposomal EPO compositions prepared under the mild conditions described in the present application exhibit improved stability, even though EPO is not substantially incorporated within the liposomes and instead essentially contained in the aqueous buffer solution of the composition. According to applicant JP

417 discloses a liposomal dispersion wherein EPO is contained within the interior of the liposome, Maitani discloses a liposomal dispersion wherein a high percentage of EPO is encapsulated within the liposomes and neither JP nor Maitani disclose EPO being dispersed within the aqueous phase solution. Further according to applicant, in Collins EPO is attached to the outer surface of the liposomes.

These arguments are not persuasive. First of all, instant claims are composition claims and not process claims. Instant claims do not recite any mild conditions as argued by applicant. With regard to EPO, the examiner once again points out that a liposome has two aqueous phases, one within the bilayer and one outside the bilayer and instant claims do not recite any percentages for EPO within the bilayer and outside the bilayer. Instant 'comprising' does not exclude EPO within the aqueous compartment of the liposomes. It should also be pointed out that though Collins calls the compositions as complexes, the method of preparation involves the addition of the protein factors (which include EPO) as aqueous solutions to the lipid and therefore, the presence of EPO as dispersed EOP in the outer aqueous medium is implicit. Applicant's arguments that JP 229 discloses glycine as stabilizer for EPO but silent in EPO being dispersed within the aqueous phase and accordingly does not cure the deficiency of JP 417 and Maitani are not persuasive since this reference is added to show that glycine offers stability to EPO in aqueous solutions. Furthermore, as noted above, applicants themselves state that that their unexpected discovery is that the liposomal EPO compositions prepared under mild conditions exhibit improved stability. From the

teachings of JP 229 one could argue that the improved stability observed by applicants is due to the stability offered by glycine and is to be expected.

3. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK